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GENERAL INTEREST



Efficacy of SARS-CoV-2 based mRNA vaccines for patients with thoracic malignancies with 6 months follow up: A prospective observational study

<u>U. Janzic</u>¹, K. Mohorcic¹, L. Mrak¹, M. Ivanovic², U. Bidovec Stojkovic³, J. Debeljak³, P. Korosec³, M. Rijavec³

¹Medical Oncology Department, University Clinic of Respiratory and Allergic Diseases Golnik, Golnik, Slovenia; ²Medical Oncology Department, University Clinical Centre Maribor, Maribor, Slovenia; ³Laboratory for Clinical Immunology and Molecular Genetics, University Clinic of Respiratory and Allergic Diseases Golnik, Golnik, Slovenia

Background: Vaccination against SARS-CoV-2 in patients (pts) with thoracic malignancies is crucial since they are at high risk of having severe COVID-19 disease course. Still, data on efficacy of vaccination in this pt population are scarce.

Methods: Prospective observational study of pts with solid cancers on active anticancer treatment (chemotherapy, immunotherapy with immune checkpoint inhibitors (ICI) or targeted therapy (TT)) that received mRNA-based SARS-CoV-2 vaccination was performed. Pts were sampled before, 2-3 weeks after the first, 2-3 weeks after the second dose, 3 and 6 months after the complete primary course of vaccination. Detection of anti-SARS-CoV-2 S1 lgG antibodies in serum was determined with commercial ELISA assay IDK®. Samples with \geq 175 ng/ml were considered positive. Here we present data on pts with thoracic malignancies.

Results: Ninety-two pts were included in the analysis. Median age at diagnosis was 63 years, 49% were female and 93% were currently receiving anticancer therapp. Pts were treated for NSCLC, SCLC and malignant pleural mesothelioma in 90%, 5% and 5%, respectively. Eighteen pts had previous exposure to COVID-19. Out of 74 COVID-19 naïve pts, seroconversion after $1^{\rm st}$ vaccination was 61%, after $2^{\rm nd}$ 96%, and seropositivity 3 and 6 months after $2^{\rm nd}$ vaccination 94% and 95%, respectively. According to treatment type, pts treated with chemotherapy, chemo + ICI, ICI allone or TT achieved seroconversion after $2^{\rm nd}$ vaccination in 100%, 83%, 96% and 100%, and mostly maintained positive levels of anti-SARS-CoV-2 S1 IgG antibodies 6 months after $2^{\rm nd}$ vaccination with 100%, 100%, 89% and 95%, respectively. However, there was a marked decrease in anti-SARS-CoV-2 S1 IgG antibody level of 69% in average 3 months after and 80% in average 6 months after the $2^{\rm nd}$ vaccination in pts with thoracic malignancies (both P < 0.001).

Conclusions: Pts with thoracic malignancies achieve high proportion of seroconversion after two doses of mRNA-based vaccines, yet, anti-SARS-CoV-2 S1 IgG antibody levels decline substantially 3 and 6 months after the 2nd vaccination, thus the 3rd dose of vaccine is reasonable to provide adequate protection against severe COVID-19 disease course.

Legal entity responsible for the study: The authors.

Funding: Slovenian Research Agency (Grant no. P3-0360).

Disclosure: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.02.113



Assessment of seroconversion after SARS-CoV2 vaccination in patients with lung cancer

<u>I.P. Trontzas</u>¹, I. Vathiotis¹, G. Gomatou¹, M. Grammoustianou¹, I. Tsamis¹, M. Anagnostakis¹, V. Sakka², G. Poulakou², K.N. Syrigos¹, E.A. Kotteas¹

¹Oncology Unit, 3rd University Clinic of Internal Medicine, Sotiria Thoracic Diseases Hospital of Athens, Athens, Greece; ²3rd University Clinic of Internal Medicine, Sotiria Thoracic Diseases Hospital of Athens, Athens, Greece

Background: SARS-CoV2 mortality rates are significantly higher in patients with lung cancer compared with the general population. However, little is known on their immunization status after vaccination.

Methods: We obtained antibody titers against SARS-CoV2 spike protein from patients with lung cancer both at baseline and at different time points after the first dose of SARS-CoV2 vaccine (three weeks — one week [T1], six weeks \pm one week [T2], 12 weeks \pm three weeks [T3], and 24 weeks \pm three weeks [T4]). Antibody titers were correlated with different clinicopathologic characteristics. Then, they were compared to a control cohort of non-lung cancer patients (Cohort A) as well as a second cohort containing healthy controls (Cohort B) at all time points and at T4, respectively. The t test or one-way analysis of variance was used to compare the means between two or more groups, respectively. All hypothesis testing was performed at a two-sided significance level of α equal to 0.05.

Results: A total of 125 patients with lung cancer were included in the analysis (96 males [74.3%], median age of 68 years [46-91]). All study participants received two vaccine doses (BNT162b2, mRNA-1273, AZD1222). Analysis of anti-SARS-CoV2 spike

protein titers showed minimal serum response at T1 (0.4 [0.4-48.6] IU/ml). Antibody response peaked at T2 (527.0 [0.4 - 2500] IU/ml) and declined over T3 (323.0 [0.4-2500] IU/ml) and T4 (141.0 [0.4-2500] IU/ml). Active smokers had lower antibody titers at T2 (p=0.04), T3 (p=0.04), and T4 (p<0.0001) compared with former or never smokers. Peak antibody titers were not associated with any other clinicopathologic characteristics. No significant differences were observed compared with Cohort A. However, lung cancer patients group exhibited significantly decreased antibody titers compared with Cohort B at T4 (p<0.0001).

Conclusions: Lung cancer patients demonstrate sufficient antibody response six weeks after first dose of vaccine against SARS-CoV2 when vaccinated with two dose vaccines. Rapidly declining antibody titers six weeks after first dose underline the need for further studies concerning a third booster dose three months after first dose in patients with lung cancer, and especially active smokers.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosure: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.02.114



COVID-19 pandemic impact on lung cancer patient's performance status and access to treatment: A comparative study pre and during COVID-19 era

R. Fernandes, M. Pina, C. Fava Gaspar, A.R. Teixeira, C. Oliveira, A. Rodrigues, I. Azevedo

Medical Oncology Department, Instituto Portugues de Oncologia do Porto Francisco Gentil, EPE (IPO-Porto), Porto, Portugal

Background: COVID-19 represents a large health care system consuming problem worldwide, and two years after its onset the real impact among non-COVID disease is still undetermined. Since the pandemic outbreak, cancer patients encountered profound changes in health care accessibility with an unknown impact in their diagnosis and treatment.

Methods: We conducted a retrospective cohort study including a total of 500 first consult patients with lung cancer in a Portuguese Cancer Center during homologous time period, pre (2019) and in the COVID-19 era (2021). Our aim was to characterize and compare both groups in relation to patient's initial performance status, disease staging and patient's conditions to initiate systemic treatment, before and during COVID-19 pandemics.

Results: We found no significant differences in age, gender distribution, time from $1^{\rm st}$ suspicious image exam to $1^{\rm st}$ consultation and staging on both groups. However, we observed a tendency towards frailty, with an increased number of patients presenting ECOG-PS >2 (26/250 in 2019 vs. 32/250), this functional deterioration explained the increased number of patients with no conditions to initiate systemic treatment and early referencing to best supportive care treatment (18% [45/250] in 2019 vs. 22% [54/250] in 2021).

Conclusions: We believe that pandemic impact in non-COVID-19 patients, particularly in lung cancer population, is still an emerging and crescent problem that societies and health care systems will need to address in coming years as a concerted effort involving increased investment in the detection and treatment of cancer patients, in order to gradually recover pre-COVID-19 health levels.

Legal entity responsible for the study: The authors.

Funding: Has not received any funding.

Disclosure: All authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.02.115



Lung cancer care in Europe during COVID-19: Findings from a global survey of patient experience

J. Fenemore

Nursing Oncology, Global Lung Cancer Coalition, Manchester, UK

Background: The Global Lung Cancer Coalition (GLCC), a partnership of 42 patient organisations across 30 nations, surveyed lung cancer patients to understand the impact of the COVID-19 pandemic on their experience of care. The global online survey examined how care pathways had changed, and how this affected patients' communication with their medical team.

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Methods: A multi-national steering group of patients, clinicians and advocates devised questions to explore: How easy patients found it to contact their medical team Whether patients had continued attending appointments in person Whether patients had experienced virtual consultations, and their view of them if so Questions were translated into multiple languages. GLCC members distributed the survey via emails and social media. Results were collated and analysed by the steering group. The GLCC produced a global report with findings for all participating countries, as well as bespoke reports for each country comparing national findings to the global picture.

Results: Responses were received from 10 European nations: Bulgaria, Denmark, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, and the UK. 494 of the 1,291 responding patients were from Europe (38%). Headline findings for Europe include: Many patients said there was no difference in how easy it was to contact their medical team. A proportion in almost all countries had found contact harder and some patients said they held back because their team was so busy Most patients had been able to see their medical team in person, but the majority in most countries also had telephone appointments. A smaller proportion of patients in only some countries had video calls The majority of patients in all countries prefer in person appointments, but many liked not having to travel to hospital. A small proportion found them difficult or said they wished to stop.

Conclusions: Conclusion As healthcare systems recover from COVID-19, lung cancer patients' perspectives on virtual consultations must be considered to ensure they work for everyone, with alternatives and support available for those who find video or telephone difficult. All patients should be encouraged to contact their medical team when they need them, despite the pandemic.

Editorial acknowledgement: Authors: Jackie Fenemore: Lung Cancer Nursing UK Maureen Rigney: G02 Foundation for Lung Cancer Win Boerckel: Cancer Care Merel Hennink: Longkanker Nederland Aoife McNamara: Irish Cancer Society Javi Mayans: Asociación Española de Afectados por el Cáncer de Pulmón Bernard Gaspar: Asociación Española de Afectados por el Cáncer de Pulmón Lauren Pretorius: Campaigning for Cancer Micaela Daniels: Campaigning for Cancer Jesme Fox: Roy Castle Lung Cancer Foundation.

Legal entity responsible for the study: The author.

Funding: Global Lung Cancer Coalition.

Disclosure: The author has declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2022.02.116

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Randomized, phase II, placebo-controlled trial of nintedanib for the treatment of radiation pneumonitis

Z.R. Moore ¹, A. Rimner ¹, S. Lobaugh ², A. Geyer ³, D.Y. Gelblum ¹, A.F. Shepherd ¹, N. Shaverdian ¹, A.J. Wu ¹, J.E. Chaft ³, M.G. Zauderer ³, C.M. Rudin ³, N. Vander Els ³, M. Chawla ³, D.R. Jones ⁴, D.M. Sopka ⁵, R. Mak ⁶, Z. Liao ⁷, D.R. Gomez ¹, Z. Zhang ², P. Paik ³

¹Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY, USA; ²Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, USA; ³Medicine, Memorial Sloan Kettering Cancer Center, New York, NY, USA; ⁴Surgery, Memorial Sloan Kettering Cancer Center, New York, NY, USA; ⁵Radiation Oncology, Lehigh Valley Health Network, Allentown, PA, USA; ⁶Radiation Oncology, Brigham and Women's Hospital, Boston, MA, USA; ⁷Radiation Oncology, MD Anderson Cancer Center, Houston, TX, USA

Background: Radiation pneumonitis (RP) is the most common dose-limiting toxicity for thoracic radiation therapy. RP can cause substantial morbidity and often progresses to permanent fibrosis. Nintedanib is used for the treatment of idiopathic pulmonary fibrosis, which shares many pathophysiological pathways with the sub-acute phase of RP. Our goal was to investigate the efficacy and safety of nintedanib added to a standard prednisone taper compared to a prednisone taper alone in reducing pulmonary exacerbations in patients with grade 2 or higher (G2+) RP.

Methods: In this phase II, randomized, double-blinded, placebo-controlled trial, patients with newly diagnosed G2+ RP were randomized 1:1 to nintedanib 150mg twice daily for 12 weeks or placebo, in addition to a standard 8-week prednisone taper. The primary endpoint was freedom from pulmonary exacerbations within one year. Secondary endpoints included total number of exacerbations and pulmonary function tests (PFTs). Kaplan-Meier analysis was used to estimate the probability of freedom from pulmonary exacerbation. The study was closed early due to slow accrual.

Results: Thirty-four patients were enrolled, three patients withdrew consent, and one was not treated. Of the evaluable 30 patients, 18 were randomized to the experimental Arm A (nintedanib + prednisone taper) and 12 to control Arm B (placebo + prednisone taper). Freedom from exacerbation at one year was 72% (CI 54%-96%) in Arm A and 40% (CI 20%-82%) in Arm B (one-sided p=0.037). In Arm A there were 16 G2+ adverse events possibly or probably related to treatment compared to five in the placebo arm. There were two deaths during the study period in arm A due to cardiac failure and progressive respiratory failure, respectively. No baseline patient characteristics were associated with freedom from exacerbations, and there were no statistically significant changes in PFTs between treatment arms.

Conclusions: After the initial onset of G2+ RP, treatment with nintedanib plus prednisone taper improved freedom from pulmonary exacerbations at one year compared to placebo plus prednisone taper. These findings show promise for the use of nintedanib in the treatment of radiation pneumonitis.

Clinical trial identification: NCT02496585.

Legal entity responsible for the study: The authors.

Funding: Boehringer Ingelheim, National Cancer Institute

Disclosure: A. Rimner: Financial Interests, Institutional, Sponsor/Funding: Boehringer Ingelheim; Financial Interests, Institutional, Research Grant: Varian Medical Systems; Financial Interests, Institutional, Research Grant: AstraZeneca; Financial Interests, Personal, Research Grant: Merck; Financial Interests, Institutional, Resear cial Interests, Personal, Research Grant: Pfizer; Financial Interests, Personal, Other, Consulting: Boehringer Ingelheim; Financial Interests, Personal, Other, Consulting: AstraZeneca; Financial Interests, Personal, Other, Consulting: Merck; Financial Interests, Personal, Other, Consulting: Cybrexa; Financial Interests, Personal, Invited Speaker, Honorarium: ResearchToPractice; Financial Interests, Personal, Other, Travel Support: Philips/Elekta: Non-Financial Interests, Personal, Advisory Board Merck; Non-Financial Interests, Personal, Leadership Role: ITMIG; Non-Financial Interests, Personal, Leadership Role: IMIG; Financial Interests, Personal, Leadership Role: ASTRO. N. Shaverdian: Financial Interests, Institutional, Research Grant: Novartis. M.G. Zauderer: Financial Interests, Institutional, Sponsor/Funding: University of Michigan; Financial Interests, Institutional, Sponsor/ Funding: Boehringer Ingelheim; Financial Interests, Institutional, Research Grant: GSK; Financial Interests, Institutional, Research Grant: Precog: Financial Interests, Institutional, Research Grant: Polaris; Financial Interests, Institutional, Research Grant: Sellas Life Sciences; Financial Interests, Institutional, Research Grant: Bristol Myers Squibb; Financial Interests, Institutional, Research Grant: Takeda: Financial Interests, Institutional, Research Grant: Curis: Financial Interests, Institutional, Research Grant: Atara; Financial Interests, Personal, Other, Consulting: Takeda; Financial Interests, Personal, Other, Consulting: GSK; Financial Interests, Personal, Other, Consulting: Aldeyra Therapeutics; Financial Interests, Personal, Other, Consulting: Novocure; Financial Interests, Personal, Other, Consulting: Ikena; Financial Interests, Personal, Invited Speaker: Medscape; Financial Interests, Personal, Person terests, Personal, Invited Speaker: Research to Practice; Financial Interests, Personal, Invited Speaker: Medical Learning Institute; Financial Interests, Personal, Invited Speaker: OncLive; Non-Financial Interests, Personal, Member of the Board of Directors: Mesothelioma Applied Research Foundation. C.M. Rudin: Financial Interests, Personal, Other, Consulting: AbbVie; Financial Interests, Personal, Other, Consulting: Amgen; Financial Interests, Personal, Other, Consulting: AstraZeneca; Financial Interests, Personal, Other, Consulting: Epizyme; Financial Interests, Personal, Other, Consulting: Genentech/Roche: Financial Interests, Personal, Other, Consulting: Ipsen: Financial Interests, Personal, Other, Consulting: Jazz; Financial Interests, Personal, Other, Consulting: Lilly; Financial Interests, Personal, Other, Consulting: Syros; Non-Financial Interests, Personal, Advisory Board: Bridge Medicines; Non-Financial Interests, Personal, Advisory Board: Earli; Non-Financial Interests, Personal, Advisory Board: Harpoon Therapeutics; Financial Interests, Personal, Member of the Board of Directors: LUNGevity; Non-Financial Interests, Personal, Advisory Board: LUNGevity. R. Mak: Non-Financial Interests, Personal, Advisory Board: AstraZeneca. All other authors have declared no conflicts of interest

https://doi.org/10.1016/j.annonc.2022.02.117

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Safety and efficacy of immmunotherapy rechallenge following a previous immune-induced interstitial lung disease

C. Joseph¹, J. Mazieres², M. Delaunay¹, A. Lusque³, J-M. Michot⁴, R. Veillon⁵, M. Wislez⁵, P. Tomasini⁷, E. Giroux-Leprieur⁸, M. Duruisseaux³, M. Pérol¹⁰, C. Decroisette¹¹, B. Duchemann¹², S. Couraud¹³, J. Milia¹, S. Collot¹⁴, G. Prevot¹, Le Payer¹⁵

¹Pulmonology Department, Hôpital Larrey, Toulouse, France; ²Thoracic Oncology Department, Centre Hospitalier Universitaire de Toulouse - Hopital Larrey, Toulouse, France; ³BEC, Institut Claudius Regaud, Toulouse, France; ⁴Drug Developpement Department, Institut Gustave Roussy, Villejuif, France; ⁵Pulmonology Department, CHU Bordeaux — Hôpital Haut Lévêque, Pessac, France; ⁶Pulmonology Department, Hôpital Cochin, Nogent Sur Marne, France; ⁷Multidisciplinary Oncology and Therapeutic Innovation Dept., AP-HM Hôpital Nord, Marseille, France; ⁸Respiratory Diseases and Thoracic Oncology Department, Hopital Ambroise Pare AP-HP, Boulogne-Billancourt, France; ⁹Chest Department, Hopital Louis Pradel, Hospices Civiles de Lyon - HCL - Lyon University Hospital Center, Lyon, France; ¹⁰Medical Oncology Dept., Centre Léon Bérard, Lyon, France; ¹¹Pulmonology Department, Le Centre Hospitalier Annecy Genevois, Annecy, France; ¹⁴Medical Oncology Department, Lyon Sud Hospital Center - HCL, Pierre-Bénite, France; ¹⁴Radiology Department, Hôpital Larrey, Toulouse, France; ¹⁵Pulmonology and Thoracic Oncology Department, Hopital Saint Joseph, Paris, France

Background: Immune checkpoint inhibitors (ICIs) are associated with immune-related adverse events. Rechallenge after a first episode of ILD remains controversial.

Methods: We conducted a multicenter retrospective cohort study of ICIs rechallenge after a first episode of an ICI-associated with interstitial lung disease (ICI-ILD). The objective was to evaluate the safety and efficacy of immunotherapy rechallenge.

Results: Thirty-two patients were included and were initially treated with anti-PD-1 monotherapy (84.4%) or in combination with anti-CTLA-4 (15.6%) and experienced grade 1 (25%), grade 2 (56.2%) grade 3 (18,8%) ICI-ILD. Most patients (90.6%) were rechallenged with anti-PD-1 monotherapy. Thirteen patients (40.6%) experienced ILD recurrence following rechallenge. Median time to recurrence of ICI-ILD after ICI rechallenge was shorter for the recurrence vs for the first episode: 0.9 (range: 0.2-8.3) vs 3.0 (0.03-35.7) months. The second episode of ICI-ILD appeared to be more severe than the first one, regarding both symptoms (38.5% vs 18.8 % of grade \geq 3 ILD), and radiological features (higher number of lobes and intensity of CT-scan lesions after centralized review). One ICI-ILD related death was reported. 53.8% of patients recurred with a similar radiological pattern. Steroids use during rechallenge was not associated with ICI-ILD recurrence risk. Objective response rate and disease stabilization under ICI rechallenge were at 18.8% and 34.4%. Progression free survival and overall survival were not statistically different in patients who experienced ICI-ILD recurrence vs not. Three months after the rechallenge, 15 patients (46.9%) had

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